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ScienceDirect

Journal of Forensic and Legal Medicine 15 (2008) 510–515

JOURNAL OF FORENSIC AND LEGAL MEDICINE

www.elsevier.com/jflm

Original Communication

Filshie clip closure: Determination of closure through the analysis of X-rays

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Received 9 May 2007; received in revised form 18 March 2008; accepted 18 May 2008
Available online 8 August 2008

Abstract

The Filshie method is a tubal occlusion method commonly used to prevent pregnancy. In medical negligence cases where it is suspected that closure of a Filshie clip may be faulty, lawyers may call on expert surgeons to assess whether or not a clip is closed on the basis of visual examination of the X-rays. However, it is not uncommon for experts to disagree. The aim of this work was to reduce the uncertainty in determining whether or not Filshie clips had been correctly closed. An estimate of the error in the estimate of the clip height was made by propagating measurement errors through a mathematical model. The effects of angle of presentation of the clip, digitisation of the image and resolution of the measurements were studied and the method was applied to two cases. The analysis indicated that measurement errors were least when the digitisation of the image was at 600 dpi, angle of presentation of the clip was less than 40° and the measurements could be made to an accuracy of ±1 pixel. Under these conditions it was possible to determine clip closure height with an error of less than ±0.2 mm.

Keywords: Female contraception; Fallopian tube; Medical negligence; Tubal occlusion; Filshie method

1. Introduction

The Filshie clip system is regarded as an effective method of female tubal ligation, but like all medical procedures the results are not always predictable and there is a generally-accepted rate of failure. In this paper, failure of the system is defined as pregnancy after the procedure, whether or not the pregnancy progresses to full term. The Filshie clip system has been used widely in Australia with great success. In Queensland alone, several thousand operations are done each year and the worldwide published statistics[1–9] indicate that a proportion of those operations will fail for reasons not attributed to the actions of the doctor. However, it is possible that some failures of the device may be due to incorrect fitting of the Filshie clips and this has led to a number of medical negligence cases against doctors.

One of the recognized causes of failure of Filshie clips occurs when the clip is incompletely closed. This can occur if the clip is closed with an incorrectly calibrated applicator or if the surgeon does not fully depress the applicator during surgery. When a Filshie clip procedure fails, one of the factors that should be determined is whether the clip had been correctly closed to within the range set by the manufacturer. Whether or not the clip applicator was calibrated is to an extent immaterial if it can be shown that the clip was closed to the correct height. If the clip can be removed from the patient, it can be examined to determine this. However, for various reasons this may be difficult and all that may remain are some X-ray images taken after the procedure of the clips in situ. In this paper, a methodology is described to estimate the closure height of Filshie clips based on X-ray images in an attempt to determine whether or not the clip is correctly closed. Some experiences with using this method are also described.

Initially developed by Casey and Filshie (US Patent No. 4,489,725), the Filshie clip system became a popular and

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1752-928X/$ - see front matter
doi:10.1016/j.jflm.2008.05.008

successful method for tubal ligation. The Filshie clip is a hinged device made of titanium lined with silicone rubber. In order to perform its function, the clip is place around the fallopian tube of the patient and is closed by an applicator. The applicator flattens the upper latch of the Filshie clip in such a way that it is extended under the lip of the lower jaw. The pressure from the silicone rubber linings of the jaw and latch lock the latch in place. The fallopian tube is firmly crushed between the jaws, occluding the tube and preventing the travel of sperm and/or eggs in the fallopian tube. Over time, necrosis of the tissue between the jaws may occur and the fallopian tubes may separate at the clip, with the ends of the tubes sealing off.

Key to the success of the Filshie clip operation is the occlusion of the fallopian tube. If this is not complete, there is a possibility of sperm passing through the partly occluded tube potentially leading to an ectopic pregnancy or if the gap is large an egg may pass unhindered to the uterus and be fertilized normally. As a result, the latch and the jaw of the Filshie clip must be pressed together to such an extent that there is no gap sufficient for the sperm to pass through the occluded fallopian tube. The degree to which the clip is closed is therefore of great interest, as it is possible for the clip to be latched, but to not be occluding the fallopian tube sufficiently to prevent pregnancy.

Closure of the clip is determined by the geometry of the applicator and clip and the degree to which the applicator is closed. The forces required to close the clip are significantly greater than those required to crush the fallopian tube and the fallopian tube should not provide significant resistance to the closure of the tube. Furthermore, the applicator is closed to a particular stop position and this should provide a repeatable closure height independent of the nature of the fallopian tube. As a result, the closure of the clip is largely unaffected by the physiology of the patient and clip closure should not be dependent on patient variability. Hence, although it is acknowledged that large biological differences in fallopian tubes exist, these differences are largely immaterial to the closure of the clip and should not significantly affect closure height.

It is well know that in a significant proportion of cases where properly performed tubal ligation procedures are carried out, pregnancy occurs after the procedure. The reported rates vary. Dominik et al.[3] studied a population of 1036 women sterilized using Filshie clips and compared this population with 1062 women sterilized using Hulka clips and found that failure rates of approximately 1 per 1000 for Filshie clips could be expected assuming that the procedure was properly performed. This compared favorably to the Hulka clip where failure rates of approximately 7 per 1000 were observed. Similar results were found by Sokal et al.[8] who studied a population of 1378 Filshie clip patients and 1355 patients treated with Tubal rings. In this study, pregnancy rates of approximately 2 per 1000 were observed in both the Filshie clip patients and those fitted with Tubal rings. In a review of world experience in the use of Filshie clips as a sterilization procedure, Penfield[6] concluded that the expected failure rate of Filshie clip sterilization procedures is 2.7 per 1000 even if the operation is properly conducted. As a result, surgeons are required to explain the known risks of a procedure to patients prior to the operation and hence patients are expected to accept the 2 per 1000 risk that they may become pregnant following the operation.

If it can be shown that the clips in the patient have been closed to the correct height, then it is hard to argue that the pregnancy had been caused by an out-of-calibration applicator. In many instances, it is not possible to measure the clips directly. Unless the clips were retrieved in an operation subsequent to the failed tubal ligation procedure, it is often unreasonable to expect to be able to retrieve the clips. In these cases, the only evidence available regarding the closure of the clips may be X-rays taken for instance as part of an Hysterosalpinogogram (HSG) procedure. The X-rays will often show the clips in situ and can be used by medical experts to evaluate the degree to which the clips have been closed. However, this evaluation is often qualitative and is based on the medical practitioner's judgment as to what is an acceptable degree of curvature regarding the upper latch of the clip. As it is not uncommon for experts to disagree, a quantitative approach to the measurement of the upper latch of the clip has been taken.

This paper presents a method for evaluating the height of closed Filshie clips on the basis of measurements from X-rays and to quantify the degree of confidence in these measurements. The application of the method is independent of the biovariability of patients. The key medico-legal question this paper attempts to address is "Was this clip closed in accordance with the expectations of the manufacturer?" and to quantify the degree of certainty of the answer. This has proven to be an important legal question and from a medico-legal perspective, if the clip can be shown to be closed in accordance with the manufacturer's expectations and is on the correct anatomical feature, then it can be argued that the surgeon has done what can reasonably be expected to ensure the success of an operation. In the following sections, the method is outlined and two examples are used to illustrate the use of the method.

2. Materials and methods

When an X-ray is taken the image on the film is distorted by a number of factors. First, the image tends to be magnified because the X-ray source approximates a point source and the film is placed at some distance behind the clip. Second, some flaring of the image may occur due to the fact that the source is finite in size. Third, the clip may present at an angle to the incident X-rays and thus will not in general provide a profile that can be simply measured. Finally, some angular distortion may occur as a result of the finite size of the clip compared with the point source of the X-rays. A typical X-ray image is as shown in Fig. 1. In this analysis flaring is ignored as are angular dis-

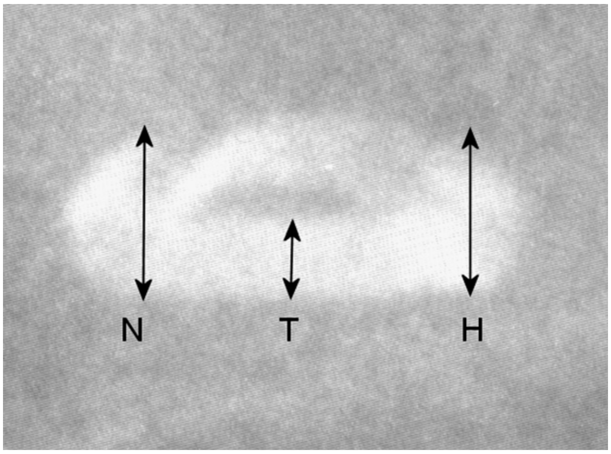

Fig. 1. Typical X-ray image of Filshie clip showing key measurements.

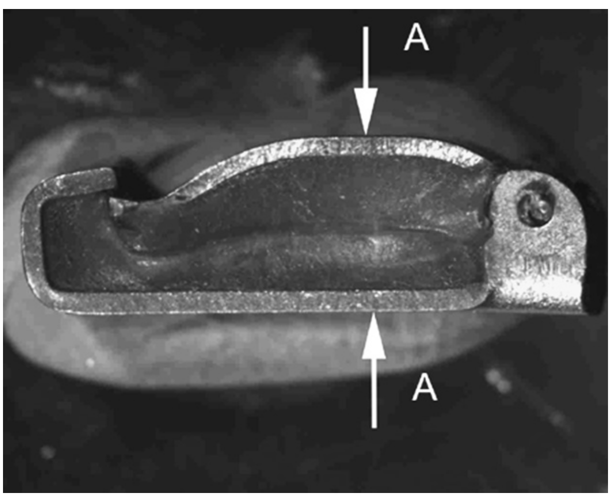

Fig. 2. Typical image of a Filshie clip showing the key measurement of clip height.

tortions. Because of the small size of the clips compared with other features and the geometry of the X-ray system, it is assumed that the X-rays are close to parallel as they pass the clip.

In this study, the X-ray images of the clips were first scanned at a resolution of 23.5 dots per mm (600 dots per inch). The image was then rotated so that the base was horizontal. Measurements from the image were taken using UTHSCSA ImageTool software.[10] Fig. 1 shows the X-ray of a clip rotated in two axes – about the horizontal axis (x-axis) and about the vertical axis (y-axis). In order to determine the angle of rotation about the x-axis, three measurements were taken: the apparent vertical distance from the base to the tip of the nose (N), the apparent thickness of the base (T) and the apparent vertical distance from the base to the top of the hinge (H). In calculating the angle of rotation, it was assumed that the dimensions of the base of the clip were standard and that the only significant difference in the dimensions from clip to clip were due to the profile of the latch. The key parameter to be estimated is the clip closure height and this is shown in Fig. 2. Using the known dimension of the clips, measurements N, T and H can be calculated in the following manner

$$\begin{aligned} H &= \lambda(h\cos\phi + b\sin\phi) \\ T &= \lambda(t\cos\phi + b\sin\phi) \\ N &= \lambda(n\cos\phi + b\sin\phi) \end{aligned} \tag{1}$$

where h is the height of the hinge, b is the width of the clip, t is the thickness of the base and n is the height of the nose of the clip. h, b and t are taken from the standard design measurements of the clip. ϕ is the angle of rotation about the x-axis and λ is the magnification of the X-ray. The three simultaneous equations to solve for two unknowns provides for some redundancy. ϕ can be determined by a solution from any two of the equations. For example,

$$\phi = \arctan\left(\frac{\left(\frac{H}{T}t - h\right)}{b\left(1 - \frac{H}{T}\right)}\right) \tag{2}$$

The magnification factor, λ, can then be determined from Eq. (1). The angle of rotation about the y-axis, θ, can then be determined in a similar manner.

Once the magnification factor, λ, and the angle of rotation about the x-axis, θ, are determined, the latch profile in the X-ray can be rotated in such a manner that it can be compared with the expected height of the latch.

One of the important considerations is the level of measurement error associated with this approach. Because of the nature of the X-ray images, it is only possible to determine each of the measurements to approximately ±2 pixels. Calculation of the measurement error in the determination of angles is made using a standard error propagation technique. The error analysis propagation technique used was as described in Eq. (3)

$$\delta K = \sqrt{\left(\frac{\partial K}{\partial x_1}\cdot\delta x_1\right)^2 + \left(\frac{\partial K}{\partial x_2}\cdot\delta x_2\right)^2 + \left(\frac{\partial K}{\partial x_2}\cdot\delta x_2\right)^2 + \cdots + \left(\frac{\partial K}{\partial x_i}\cdot\delta x_i\right)^2} \tag{3}$$

where K is a value calculated on the basis of x_1, x_2, x_3, $\ldots, x_i$ measured values and δK, $\delta x_1, \delta x_2, \delta x_3, \ldots, \delta x_i$ are the measurement errors in those figures and will either be the standard manufacturing tolerances in the clips or the

measurement errors in measurements taken from the X-rays. This method of calculating measurement error is commonly used to provide a reasonable estimate of expected error in the calculated value.[11] Simple addition of the contributions of each measurement tends to overestimate the error in a manner that statistically is unlikely. The method described in Eq. (3) assumes that errors will often cancel one another out or will not all tend to be at the extremity of the error range and hence a lower value than suggested by simple addition of the errors can reasonably be expected.

From Eq. (3), it can be shown that the errors in determination of ϕ increase significantly as ϕ increases. For a typical angle of rotation of 1°, the error in angle determination is $\pm 1°$. This would lead to small levels of error in the determination of the latch profile. If the angle of rotation is 40°, measurement errors will be approximately $\pm 2.5°$. Propagation of errors through the rotation of the top latch profiles in this case can lead to high levels of measurement error in the final latch profile. Therefore, as the angles ϕ and θ increase, confidence in the rotated profile from the X-rays decreases.

The key measurement in determining clip closure height is the closed height of the clip, which is shown as measurement A in Fig. 2. The accepted values of measurement A for a correctly closed clip are 3.8–4.2 mm. This value can be estimated using the following equation:

$$A = \frac{\left(\left(\frac{A^*}{\lambda}\right) - b\sin(\phi)\right)}{\cos(\phi)} \quad (4)$$

3. Results

Using Eqs. (1), (2), and (4), it is possible to determine an estimate of the magnification of the clip (λ), the angle of presentation of the clip (ϕ) and the closed clip height (A). A question of major importance, however, is the reliability of this figure. There is inherent variability in the manufacturing of the clips, but this variability is quite small. The largest source of error in the calculations is in the measurement of N, T, H and A^* from the X-rays. Even magnified on X-ray film, the clips are typically only 15 mm in size and hence measurements need to be accurate. The sharpness of the image is also very important in the calculation as images that are not sharp tend to introduce significant uncertainty into the measurement of N, T, H and A^*.

Errors have been calculated first by calculating errors in ϕ and λ. These errors were then propagated through the calculation of A as shown in Eq. (4). As the images were digitized, the measurements on the images are limited in accuracy to the resolution of the digital image. Fig. 3 shows the effect of digital resolution on the measurement error as a function of angle of presentation of the clip to the X-ray film. These calculations were made assuming that the edges of the clip can be determined to ± 1 pixel. As can be seen, the measurement error increases significantly as the angle of presentation of the clip increases. Furthermore, it can be seen that imaging at 600 dots per inch provides significantly lower measurement errors than the other two resolutions. As the value of A should lie between 3.8 and 4.2 mm, an error of greater than ± 0.25 mm is significant and suggests that scanning resolutions of 150 dpi are of limited value. Even at the highest resolution, at angles of presentation greater than 45°, the measurement errors become significant.

The accuracy to which the edges of the clip can be determined is also important and Fig. 4 shows how the accuracy of edge determination affects the measurement error for 600 dpi resolution. The curve marked "0" represents the case where the values of N, T, H and A^* are determined

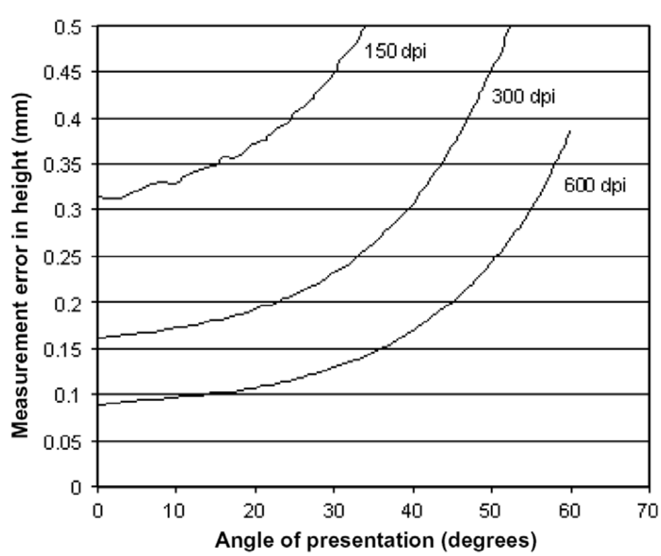

Fig. 3. Effect of image resolution and angle of presentation of the clip on measurement error in the clip height. For clip closed to 4.20 mm height and N, T, H and A^* measured to ± 1 pixel.

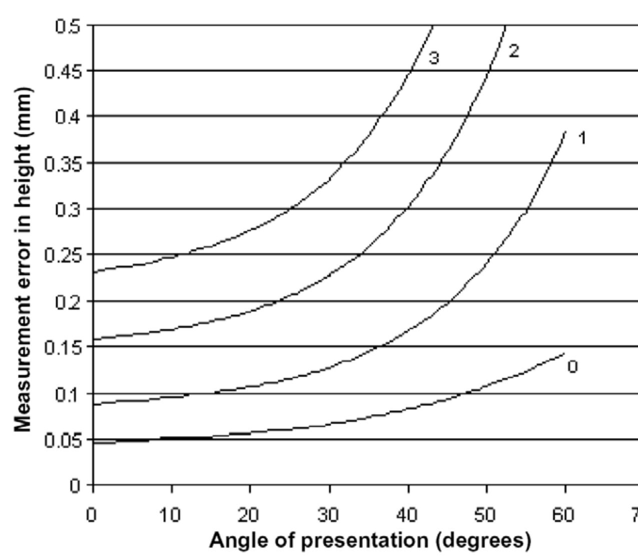

Fig. 4. Effect of measurement resolution (in pixels) and angle of presentation of the clip on measurement error in the clip height. For clip closed to 4.20 mm height and image resolution of 600 dpi.

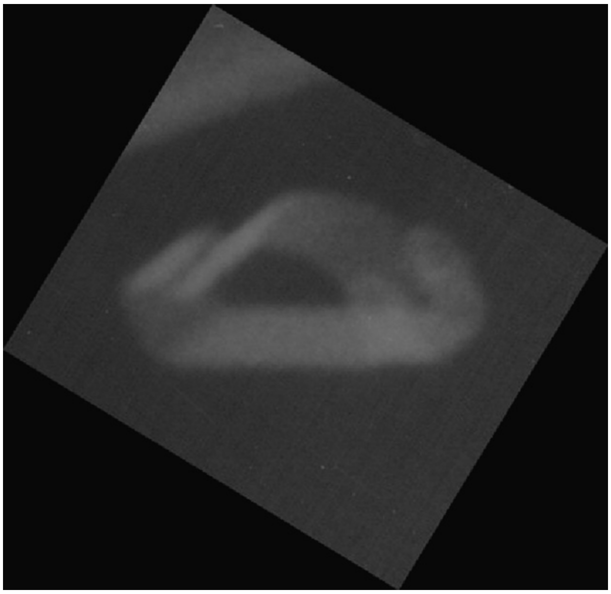

Fig. 5. Image of Filshie clip rotated for measurement (Clip 1).

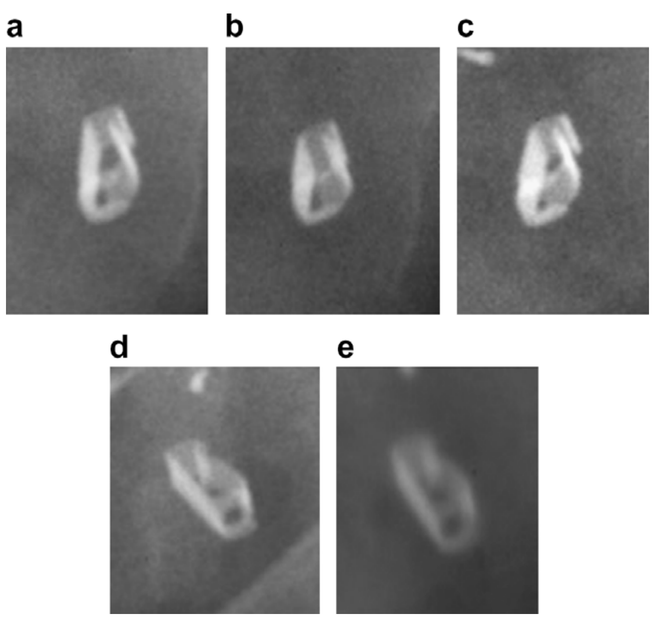

Fig. 6. Five images of one Filshie clip taken from X-rays (Clip 2).

exactly. Although only of theoretical interest, it shows the uncertainty in A due to the manufacturing tolerances in the clips. The other three curves represent where the values of N, T, H and A^* are measured to ± 1, ± 2 and ± 3 pixels.

Figs. 5 and 6 show X-rays of two clips that were taken from two different cases. These clips are used here to demonstrate the application of the method. As can be seen, the clips are rotated with respect to the viewing plane. These clips are identified as Clip1 and Clip 2. In the case of Clip 1, only one image of the clip was obtained and was scanned at 600 dpi. The clip showed a pronounced doming of the upper latch. Analysis of the clip using the above technique indicated that the average angle of rotation about the x-axis was 26.7°. Calculation of A based on the X-ray image gave a clip closure height of 4.91 mm ± 0.12 mm. The analysis therefore confirmed that the clip was not closed to the correct height. At this relatively large angle, the margin of error is large and although the result is clear even after taking into account the reported error, there may be cases where although the calculated value may indicate that the clip is either closed or not closed, the error may give significant doubt.

Fig. 6 shows five images of the one clip. This is from multiple X-rays taken during an HSG. In all five cases, the angle at which the clip was presented in the X-ray was not optimal and the scanned resolution was only 150 dpi. The results for these clips are as shown in Table 1.

Based on the calculated values in Table 1 the standard deviation of mean is 0.16 mm. However, the measurement error of each of the measurements is as shown in Table 1 and the average measurement error for the calculation is 0.40 mm, suggesting that there is little value in the calculations. However, this does not properly address the issue of measurement error as the averaging of the five independent results should be expected to reduce the measurement error. If Eq. (3) is applied to the calculation of mean value of closure height, the propagation of the measurement errors gives a measurement error estimate of 0.18. As 4.20 mm is the upper value of the acceptable range for closure heights, there is still some room for interpretation as to whether the closure height is adequate. However, a clearer view of the level of closure and the associated uncertainty has been obtained from these calculations.

4. Discussion

The Filshie clip tubal occlusion procedure is a well established method for sterilization. However, a number of well publicized failures of procedures and the TGA announcement regarding calibration of applicators have led to a number of actions in the Courts. In many of these cases, the Plaintiff will attempt to convince the Courts that negligence on the part of the medical practitioner has occurred. Many plaintiffs have used the TGA based information regarding improper calibration of the applicator to argue that if the applicator was not properly calibrated or serviced at the recommended intervals, the failure of the operation can be attributed to poor closure of the clip. The determination of whether or not a clip is properly closed is an importance piece of evidence for the Court in these cases. If it can be shown that the clips are correctly closed, the argument regarding calibration of the applicator can be nullified.

The procedures outlined above provide an effective method of determining whether or not clips are properly closed, either by the physical measurement of the clips or by measurement of X-rays. However, due to the errors associated with the measurement from X-rays, an evaluation of the effects of these measurement errors on the latch

Table 1
Calculated clip heights and measurement errors for Clip 2

Image	ϕ (°)	Calculated closure height (mm)	Measurement error (mm)
a	21.1	4.24	0.38
b	21.0	4.41	0.38
c	34.3	4.17	0.50
d	17.8	3.97	0.36
e	15.9	4.23	0.36
Average		4.20	

profiles should be presented in order to provide convincing evidence of the level of closure of the clip.

5. Conclusion

The method described here provides a satisfactory method for estimating the clip closure height of Filshie clips based on X-ray images. The analysis indicated that measurement errors were least when the digitisation of the image was at 600 dpi, angle of presentation of the clip was less than 40° and the measurements could be made to an accuracy of ± 1 pixel. Under these conditions it was possible to determine clip closure height with an error of less than ± 0.2 mm. If multiple images are taken the expected error can be reduced further. In reporting the result of such an examination, it is recommended that the errors in the estimate should be presented as well as the calculated value of closure height, as this helps establish confidence in the result.

No attempt has been made in this paper to address quantitatively the issue of the efficacy of the closure of Filshie clips to particular heights. The efficacy of clip closure to within the manufacturer's expectations has been addressed elsewhere by the manufacturer. There is only limited data on the efficacy of closure outside of these limits and no attempt to address this is made in this paper except in so far as to indicate that the likelihood of failure of the procedure can be expected to increase with the degree to which the clip closure height is outside the manufacturers limits.

Acknowledgement

The author would like to thank Mr. Mitchell Read, formerly of Cooper Grace Ward, for his support and useful discussions.

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